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# The “Reasonable Plant” Test: When Progress Outruns the Constitution

Max Stul Oppenheimer\*

## INTRODUCTION

As the world searches for new sources of energy, attention has focused on renewable sources, such as plants. One approach to motivating investments in new technology is to provide limited term monopolies through the patent statute. With the passage of the Townsend-Purnell Plant Patent Act (PPA)<sup>1</sup> in 1930, the United States became the first country in the world to provide a form of patent protection for plants.<sup>2</sup> At the time, Francis Crick was a student<sup>3</sup> and James Watson had just celebrated his second birthday<sup>4</sup>—their discovery of the helical structure of DNA was more than twenty-two years in the future.<sup>5</sup>

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<sup>1</sup> . Townsend-Purnell Plant Patent Act, ch. 312, § 1, 46 Stat. 376 (1930) (codified as amended at 35 U.S.C. § 161 (2000)) [hereinafter PPA].

<sup>2</sup> . “Plants were first explicitly brought within the scope of patent protection in 1930 when the PPA included ‘plants’ among the useful things subject to patents.” J.E.M. AG Supply v. Pioneer Hi-bred Int’l, 534 U.S. 124, 132 (2001). Even today, international patent harmonization agreements allow countries to deny patent protection to plants. “Members may . . . exclude from patentability . . . plants and animals other than micro-organisms . . .” Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C art. 27(3)(b), Apr. 15, 1994, available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf).

<sup>3</sup> . NobelPrize.org, Francis Crick: The Nobel Prize in Physiology or Medicine 1962, [http://nobelprize.org/nobel\\_prizes/medicine/laureates/1962/crick-bio.html](http://nobelprize.org/nobel_prizes/medicine/laureates/1962/crick-bio.html) (last visited Mar. 15, 2008).

<sup>4</sup> . NobelPrize.org, James Watson: The Nobel Prize in Physiology or Medicine 1962, [http://nobelprize.org/nobel\\_prizes/medicine/laureates/1962/watson-bio.html](http://nobelprize.org/nobel_prizes/medicine/laureates/1962/watson-bio.html) (last visited Mar. 15, 2008).

<sup>5</sup> . Steve Sternberg, *Double Helix Unlocked Key to Life*, USA TODAY,

Convinced that advances in agriculture deserved patent protection, Congress attempted to accommodate the core concepts of patent law to the technology of plant propagation that existed at the time, in essence defining a plant by its physical rather than genetic characteristics.<sup>6</sup> This required bending traditional patent rules, but although Congress gave plant patent applicants the necessary latitude, it also required them to use reasonable efforts to meet the standard rules.<sup>7</sup>

Developments in biotechnology since 1930 have been dramatic. Scientific advances have not only undercut the need for the special rules created by the PPA but have also created a trap, which may deprive modern inventors of protection for the development of novel plants. Moreover, while new applicants can avoid it, the owners of thousands of issued plant patents have fallen into the trap and cannot remedy the error unless Congress provides relief.<sup>8</sup>

This article describes the enduring core principles of utility patent law and identifies those that posed special problems for the agriculture industry in 1930 and led to the adoption of a *sui generis* plant patent law. It then demonstrates that, although the statute which controls plant patents has not changed significantly since its adoption in 1930, changes in biotechnology have in effect rewritten the requirements for patentability in a way which renders most recently granted plant patents invalid. Finally, it demonstrates how future applicants can avoid the trap which has been created by advancing technology, and proposes changes in the statute which could save those patents already issued and, in the process, improve the examination of plant patent applications and provide stronger protection for the agriculture industry.

## I. CORE PRINCIPLES OF U.S. PATENT LAW

While U.S. patent law has been amended several times since 1930,<sup>9</sup> certain core principles have remained the

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Feb. 24, 2003, at D01.

<sup>6</sup> . Rev. Stat. § 4886, as amended by Act of May 23, 1930, ch. 312, § 1, 46 Stat. 376 (current version split between 35 U.S.C. §§ 101 & 161 (2000)).

<sup>7</sup> . *Id.*

<sup>8</sup> . See *infra* Part V, notes 120–122 and accompanying text.

<sup>9</sup> . See, e.g., 35 U.S.C. § 101 (2000).

same and could not be changed without fundamentally altering the system. The power to create a patent system arises under Article I Section 8 of the Constitution, which authorized Congress to reward innovation by granting monopolies on inventions for a limited time.<sup>10</sup> The power is exercised in Title 35 of the U. S. Code.<sup>11</sup>

Three types of patents are authorized: utility patents, design patents, and plant patents.<sup>12</sup> The utility patent provisions authorize granting patents for inventions within one of four classes enumerated in the statute;<sup>13</sup> the design patent provisions authorize granting patents for ornamental designs;<sup>14</sup> and the plant patent provisions authorize granting patents for distinct and new varieties of plants that have been asexually reproduced.<sup>15</sup>

All three types of patents share (and have shared since their inception) certain core patent principles. All require disclosure, and eventually publication, of the claimed

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<sup>10</sup> . "The Congress shall have Power . . . to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. 1, § 8, cl. 8. For a detailed analysis of how the clause entered the Constitution, see Walterscheid, *To Promote the Progress of Science and Useful Arts: The Background and Origin of the Intellectual Property Clause of the United States Constitution*, 2 J. INTELL. PROP. L. 1, 31-34 (1994).

<sup>11</sup> . 35 U.S.C. (2000).

<sup>12</sup> . "Patents issued under § 161 are referred to as 'plant patents,' which are distinguished from § 101 utility patents and § 171 design patents." J.E.M. AG Supply v. Pioneer Hi-bred Int'l, 534 U.S. 124, 133 n.5 (2001).

<sup>13</sup> . "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, . . . may obtain a patent . . . ." 35 U.S.C. § 101 (2000). Certain types of inventions that fall within one of these so-called statutory categories are not patentable under judicially created exceptions. Under current Supreme Court caselaw "Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." Gottschalk v. Benson, 409 U.S. 63, 67 (1972). Laws of nature, natural phenomena, and abstract ideas are also unpatentable. Diamond v. Diehr, 450 U.S. 175, 185 (1981). "[Phenomena of nature] . . . are part of the storehouse of knowledge . . . . They are manifestations of laws of nature, free to all men and reserved exclusively to none." Funk Bros. Seed v. Kalo Inoculant, 333 U.S. 127, 130 (1948).

<sup>14</sup> . 35 U.S.C. § 171 (2000).

<sup>15</sup> . 35 U.S.C. § 161 (2000). Tuber propagated plants were excluded by the statute for political reasons. See *infra* note 66 and accompanying text.

invention.<sup>16</sup> The fundamental bargain is the inventor's surrender of the details of an innovation in exchange for the patent, thereby putting the public in possession of information which the inventor could have kept confidential and giving the inventor an assured term of exclusive control over the invention.<sup>17</sup> The bargain assures that the technology will not be lost.<sup>18</sup> The vehicle for providing the required disclosure is the filing of a written application with the Patent and Trademark Office (PTO).<sup>19</sup> The application process is designed to assure that the public has gotten fair value in the bargain; it requires determinations that the applicant is providing something the public did not already have<sup>20</sup> and the applicant has provided an enabling description of the invention so that, once the patent expires, the public will be able to make and use the invention.<sup>21</sup> In addition, the application must include claims which put competitors on notice as to what they can and cannot do.<sup>22</sup> Thus, these core principles establish a system with the following characteristics:

1. The applicant for a patent must provide the patent office with enough information to determine whether what is claimed is in fact new and not obvious—this assures that the public does not pay the price of granting a monopoly for something in which it already has or, in the ordinary

<sup>16</sup> . 35 U.S.C. § 112 (2000); 35 U.S.C. § 122 (2000).

<sup>17</sup> . The patent owner's control is exclusive, meaning the right to exclude, but not exhaustive—the patent owner can only prevent others from making, using, selling or importing the patented invention. 35 U.S.C. § 154(a) (2000).

<sup>18</sup> . *Ex parte* Moore, 115 U.S.P.Q. 145, 147 (Bd. Pat. App. & Interf. 1957) (awarding inventorship to one who reproduced a peach tree over the first to notice the tree, since the objective of advancing the progress of science and useful arts was furthered by the applicant, whose actions had preserved for posterity a variety that otherwise would have been lost).

<sup>19</sup> . Regulations governing review of patent applications are contained in Volume 37 of the Code of Federal Regulations, see 37 C.F.R. (2007), and specific internal rules governing the examination of patent applications are contained in the Manual of Patent Examining Procedure (MPEP), U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (8th ed. 2001, rev. Sept. 2007) [hereinafter MPEP].

<sup>20</sup> . The claimed invention must be novel, 35 U.S.C. § 102 (2000), and non-obvious, 35 U.S.C. § 103 (2000).

<sup>21</sup> . The application must be sufficiently detailed to allow one of ordinary skill in the relevant field to make and use the invention. 35 U.S.C. § 112 (2000).

<sup>22</sup> . *Id.*

course of events, would have access to. Patents have always been limited to novel inventions.<sup>23</sup> As an incentive to add to public knowledge, a patent cannot be granted on something which would restrict something already available to the public<sup>24</sup> or which would be obvious to others of ordinary skill in the relevant field.<sup>25</sup> As explained by the Supreme Court in *KSR International v. Teleflex*, “Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.”<sup>26</sup>

2. The applicant must provide sufficient detail that (once the patent expires) others will be able to make and use the invention.<sup>27</sup>

3. The applicant must specifically claim the invention, both so that the patent office can focus its evaluation of patentability and so that, if issued as a patent, others will

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<sup>23</sup> . 35 U.S.C. § 101 provides: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101 (2000).

35 U.S.C. § 102 provides:

A person shall be entitled to a patent unless—

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . .

<sup>24</sup> . *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 6 (1966).

<sup>25</sup> . 35 U.S.C. § 103(a) (2000) (“A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”).

<sup>26</sup> . 127 S. Ct. 1727, 1732 (2007).

<sup>27</sup> . 35 U.S.C. § 112 (2000) (“The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.”).

know what they are excluded from making, using, selling or importing.

Under utility patent law (as it exists today and as it existed in 1930), claims which the patent office determines comply with the statutory requirements may be issued as a patent. The issued patent gives its owner the right to stop others from making, using, or selling products (or processes) incorporating the claimed invention during the term of the patent.<sup>28</sup>

## II. THE PROBLEM OF PLANTS CIRCA 1930

Prior to enactment of the PPA, it was commonly believed that the general utility patent rules posed special problems when applied to plants. As explained by the Supreme Court,

[p]rior to 1930, two factors were thought to remove plants from patent protection. The first was the belief that plants, even those artificially bred, were products of nature for purposes of the patent law. . . . The second obstacle to patent protection for plants was the fact that plants were thought not amenable to the "written description"<sup>[29]</sup> requirement of the patent law.<sup>30</sup>

As the Supreme Court has since made clear, those fears were unfounded: plants can be covered under both

<sup>28</sup> . The claims must define "the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 (2000). Post-1930 revisions to the statute added importation to the list of activities a patent owner may control. 35 U.S.C. § 154 (2000).

<sup>29</sup> . 35 U.S.C. § 112 requires that a patent application describe the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art" to make and use it. 35 U.S.C. § 112 (2000).

<sup>30</sup> . *Diamond v. Chakrabarty*, 447 U.S. 303, 311-12 (1980). See also David G. Scalise & Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT'L L. 83, 91 (1995) ("When a new plant differed from the old only in color, scent or texture, it was almost impossible to satisfy the written description requirement. Consequently, plant breeders were denied substantive protection for their discoveries, derailing innovation in this field."); Anne E. Crocker, *Will Plants Finally Grow Into Full Patent Protection on an International Level?: A Look at the History of U.S. and International Patent Law Regarding Patent Protection for Plants and the Likely Changes After the U.S. Supreme Court's Decision in J.E.M. Ag Supply v. Pioneer Hi-Bred*, 8 DRAKE J. AGRIC. L. 251, 257 (2003) ("One important feature of the PPA is that it helped plant breeders overcome the barrier of the written description requirements for obtaining a utility patent. Developments in traditional plant breeding were hard to record on paper with sufficient detail to satisfy the written requirements of § 112, yet generally these developments could easily be seen with the naked eye.").

the specific provisions created by the PPA<sup>31</sup> and, if they meet the requirements of the general utility provisions,<sup>32</sup> under 35 U.S.C. § 101.<sup>33</sup> The specific provisions of the Plant Patent Act do not preempt the general provisions of the utility patent statute,<sup>34</sup> plant materials are clearly compositions of matter (or manufactures)<sup>35</sup> and, in *Diamond v. Chakrabarty*, the Supreme Court rejected the argument that living matter was implicitly excluded from statutory subject matter.<sup>36</sup>

When, acting in the erroneous<sup>37</sup> belief that plants were not patentable, Congress concluded that agricultural advances should be afforded the same type of protection as technological inventions,<sup>38</sup> it faced several challenges in fitting 1930s plant technology into the framework of the patent statute.

#### A. COULD PLANTS BE STATUTORY SUBJECT MATTER?

The first challenge was whether plants fit the requirements of statutory subject matter.<sup>39</sup> Although the line of Supreme Court cases defining the “natural phenomenon” exclusion from statutory subject matter had not yet been decided,<sup>40</sup> it was generally believed that

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<sup>31</sup> . 35 U.S.C. § 171 (2000).

<sup>32</sup> . “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent . . .”

<sup>33</sup> . J.E.M. Ag Supply v. Pioneer Hi-Bred Intern., 534 U.S. 124, 145 (2001).

<sup>34</sup> . *Id.*

<sup>35</sup> . *Id.* at 147. See also *Ex parte Hibberd*, 227 U.S.P.Q. 443, 444 (Bd. Pat. App. & Interf. 1985).

<sup>36</sup> . 447 U.S. 303 (1980).

<sup>37</sup> . While the belief that plants were not patentable may have been erroneous, Congress was certainly correct that the practical problems of complying with the patent requirements in 1930 would have been almost impossible for plants. “In 1930, no written description could have enabled creation of a plant, even if the ancestry and techniques of cross-pollination were known—it was not possible to produce the plant from a disclosure contemplated by 35 U.S.C. § 112 for other types of manufactured articles. Thus, a reasonably complete description of the new plant variety is all that could be required.” *In re LeGrice*, 301 F.2d 929, 935 (C.C.P.A. 1962).

<sup>38</sup> . S. REP. NO. 71-315, at 1 (1930).

<sup>39</sup> . See *supra* notes 12–14, 29–38 and accompanying text.

<sup>40</sup> . See *Funk Bros. Seed v. Kalo Inoculant*, 333 U.S. 127, 130 (1948) (noting that phenomena of nature are part of the storehouse of nature



plants were unpatentable,<sup>41</sup> even those “made by man.”<sup>42</sup> The dissent in *Laboratory Corporation of America v. Metabolite Labs*<sup>43</sup> explains the philosophy behind exclusion of natural phenomena from patentable subject matter:

The relevant principle of law “[e]xclude[s] from . . . patent protection . . . laws of nature, natural phenomena, and abstract ideas” . . . .

The justification for the principle does not lie in any claim that “laws of nature” are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming; . . . and that research may prove of great benefit to the human race. Rather, the reason for the exclusion is that sometimes *too much* patent protection can impede rather than “promote the Progress of Science and useful Arts,” the constitutional objective of patent and copyright protection. . . .

The problem arises from the fact that patents do not only encourage research by providing monetary incentives for invention. Sometimes their presence can discourage research by impeding the free exchange of information . . . .<sup>44</sup>

## B. COULD A PLANT BE DESCRIBED AND ENABLED?

The second problem facing a potential applicant for a patent on a plant was how to meet the requirement that the invention be described and enabled—how to provide a written patent application which would satisfy the second core principal of putting the invention in the public domain once the patent expired.<sup>45</sup> While an applicant could certainly point out characteristics which distinguished their new plant from other plants, often these characteristics would be difficult to establish objectively, as indicated by early plant patents issued under the 1930 statute. (For

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and free for all to use); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (noting that phenomena of nature are not patentable because they are the basic tools for scientific and technological work).

<sup>41</sup> . *J.E.M. Ag Supply v. Pioneer Hi-bred Int'l*, 534 U.S. 124, 133 (2001), although that belief was wrong; *Diamond v. Chakrabarty*, 447 U.S. 303, 311–12 (1980).

<sup>42</sup> . As explained by the Supreme Court “Prior to 1930, two factors were thought to remove plants from patent protection. The first was the belief that plants, even those artificially bred, were products of nature for purposes of the patent law. . . .” *Chakrabarty*, 447 U.S. at 311–12. *Chakrabarty* held that the patent statute extended to “anything under the sun made by man”, including living organisms. *Id.* at 309.

<sup>43</sup> . 548 U.S. 124 (2006).

<sup>44</sup> . *Id.* at 127 (Breyer, J., dissenting) (internal citations omitted).

<sup>45</sup> . See INTRODUCTION, *supra*.

example, "good flavor,"<sup>46</sup> "superior reproductive and keeping qualities,"<sup>47</sup> "extreme hardiness,"<sup>48</sup> "superior producing qualities,"<sup>49</sup> or "firmness of flesh,"<sup>50</sup> or whose color is "between red and carmine,"<sup>51</sup> or which ripens late<sup>52</sup> were characterizations used.) Even if that problem could have been overcome with standardized terms, a second element of the application requirement could not have been met in 1930: enablement. In a case which was decided after the Plant Patent Act was enacted, the Patent Office Board of Interference Examiners noted that "the mere filing of an application for a patent for a new variety of plant would not enable anyone to reproduce such a plant."<sup>53</sup> The same principle led to the Court of Customs and Patent Appeal's decision (again following enactment of the Plant Patent Act) that a photograph of a rose bush could not defeat a patent on the same rose bush since the photograph could not enable the public to produce the plant:<sup>54</sup>

[I]t must be borne in mind that there are inherent differences between plants and manufactured articles. Should a plant variety become extinct one cannot deliberately produce a duplicate even though its ancestry and the techniques of cross-pollination be known. Manufactured articles, processes, and chemical compositions when disclosed are, however, susceptible to man-made duplication. . . .

In the case of manufactured articles, processes and chemical compositions, a different situation prevails. Written descriptions and drawings in publications can often enable others to manufacture the article, practice the process or produce the chemical composition.<sup>55</sup>

<sup>46</sup> . U.S. Plant Patent No. 47 (issued Nov. 29, 1932) (pecan).

<sup>47</sup> . U.S. Plant Patent No. 3 (issued Oct. 20, 1931) (carnation).

<sup>48</sup> . U.S. Plant Patent No. 99 (issued June 26, 1931) (hybrid barberry).

<sup>49</sup> . U.S. Plant Patent No. 11 (issued Mar. 22, 1932) (hybrid tea rose).

<sup>50</sup> . U.S. Plant Patent No. 18 (issued July 19, 1932) (plum).

<sup>51</sup> . U.S. Plant Patent No. 8 (issued Feb. 23, 1932) (rose).

<sup>52</sup> . U.S. Plant Patent No. 7 (issued Feb. 16, 1932) (peach).

<sup>53</sup> . *Dunn v. Ragin v. Carlile*, 50 U.S.P.Q. 472, 474 (Bd. Pat. App. & Interf. 1941).

<sup>54</sup> . *In re LeGrice*, 301 F.2d 929 (C.C.P.A. 1962). The decision, rendered in the same year that Watson and Crick received the Nobel Prize for their discovery of the structure of DNA, explicitly left open the possibility that in some future case a printed publication might be enabling, a remarkable insight.

<sup>55</sup> . *Id.* at 935.

## C. COULD A PLANT BE DISTINGUISHED FROM "PRIOR ART" PLANTS?

Yet another challenge to obtaining a patent for a plant was posed by the core requirement that patents are not granted to inventions already available to the public.<sup>56</sup> In order to satisfy this requirement, there must be some way of determining what the public already has access to and how it differs from the claimed invention. In the later case of *Graham v. John Deere*<sup>57</sup> the Supreme Court explained the test for determining whether an invention was too close to already-available technology to be patentable:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.<sup>58</sup>

Such a test requires that it be possible to identify the relevant characteristics in the prior art and in the claimed invention, and then to make a meaningful comparison between them. As is apparent from the types of patents granted shortly after enactment of the Plant Patent Act,<sup>59</sup> this would have posed a challenge in the context of plants. The types of characteristics being claimed as distinguishing the applicants' plants would have required subjective determinations and not have been amenable to differentiation from prior art plants.

## D. COULD CLAIMS BE PRECISE ENOUGH TO IDENTIFY THE INVENTION?

Closely related to the problem of distinguishing the claimed plant from pre-existing plants (and specifically, whether a prior publication enables the claimed plant) is the problem of how to define the claimed plant in such a way that the public can tell what is being claimed. A potential competitor is, under core patent principles, entitled to know what is available for use and what would constitute infringement.<sup>60</sup> Distinguishing an allegedly

<sup>56</sup> . This requirement is currently set forth in 35 U.S.C. §§ 102-03. In 1930, the requirement would have been found in *Hotchkiss v. Greenwood*, 11 How. 248 (1851).

<sup>57</sup> . 383 U.S. 1 (1966).

<sup>58</sup> . *Id.* at 17. The section referred to in the decision was not enacted until 1952, however, in *Deere* the Court held that enactment of § 103 did not change the law with respect to obviousness.

<sup>59</sup> . See *supra* text accompanying notes 46-52.

<sup>60</sup> . See INTRODUCTION, *supra*.

infringing plant from a patented plant would present exactly the same difficulties as distinguishing a claimed new plant from pre-existing plants.

### III. THE 1930 SOLUTION: SPECIAL RULES FOR PLANTS

Congress addressed these concerns in the 1930 PPA, which amended general utility patent law to provide:

Any person who has invented or discovered any new and useful art, machine, manufacture or composition of matter, or any new and useful improvements thereof, *or who has invented or discovered and asexually reproduced any distinct and new variety of plant, other than a tuber-propagated plant*, not known or used by others in this country, before his invention or discovery thereof, . . . may . . . obtain a patent therefor;<sup>61</sup>

"No plant patent shall be declared invalid for noncompliance . . . if the description is as complete as is reasonably possible;"<sup>62</sup>

and to provide: "Every patent shall contain . . . a grant to the patentee . . . of the exclusive right to make, use, and vend the invention or discovery (*including in the case of a plant patent the exclusive right to asexually reproduce the plant*)."<sup>63</sup> That enactment was intended to address each of the problems posed above.

#### A. THE STATUTORY SUBJECT MATTER "SOLUTION"

Congress resolved the issue of whether plants could be statutory subject matter simply by declaring it so under the broad authority granted by the Constitution to promote scientific progress.<sup>64</sup> Congress limited protection to plants

<sup>61</sup> . Act of May 23, 1930, ch. 312, sec. 1, § 4886, 46 Stat. 376 (emphasis added). The comparable provision of the current patent statute is found in 35 U.S.C. § 161 (2000) ("Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title. The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided."). The 1954 revision, which created the above language, made explicit that plants found in an uncultivated state were not patentable. Act of Sept. 3, 1954, ch. 1259, 68 Stat. 1190.

<sup>62</sup> . Act of May 23, 1930, ch. 312, sec. 2, § 4888, 46 Stat. 376.

<sup>63</sup> . Act of May 23, 1930, ch. 312, sec. 1, § 4884, 46 Stat. 376 (current version at 35 U.S.C. § 163 (2000)) (emphasis added).

<sup>64</sup> . The Constitutional grant, "Congress shall have Power . . . to Promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective

reproduced asexually. The rationale is that asexual propagation by divisions or cuttings produces clones, each of which is identical to the parent plant and to all other cuttings or clones taken from the parent, while the production of seeds by cross-pollination does not assure a true new plant variety having the characteristics desired.<sup>65</sup> Congress also carved out an exception for tuber-propagated plants, accepting the argument that patents should not be allowed to control the part of the plant which was ultimately sold for food.<sup>66</sup> In addition, the core patent principle which precludes patenting naturally occurring phenomena would translate, in the plant patent system, to a prohibition on patenting uncultivated plants, and Congress believed it had done so.<sup>67</sup>

In 1952, the patent statute was comprehensively revised and plant patents placed into a separate chapter, 15 of Title 35.<sup>68</sup> The United States Supreme Court explained,

This was merely a housekeeping measure that did nothing to change the substantive rights or requirements for a plant patent. A "plant patent" continued to provide only the exclusive right to asexually reproduce a protected plant, and the description

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Writings and Discoveries," U.S. CONST. art. I, § 8, cl. 8, is arguably limited to statutes which "promote progress," but it would be hard to argue that providing incentives for agricultural innovation falls outside that mandate.

<sup>65</sup> . *In re LeGrice*, 301 F.2d 929 (C.C.P.A. 1962); *accord* *Yoder Bros. v. Cal.-Fla. Plant Corp.*, 537 F.2d 1347 (5th Cir. 1976), *cert. denied* 429 U.S. 1094 (1977) ("After a breeder has successfully isolated a new variety, the only way he can preserve his creation is by means of asexual reproduction . . . . Since a cutting is genetically identical to the parent plant, it will develop into a plant whose characteristics match the parent's exactly, so long as the same environmental conditions obtain."); *id.* at 1380 ("Asexual reproduction is literally the only way that a breeder can be sure he has reproduced a plant identical in every respect to the parent."). However, a contemporary text notes that "[i]n general, plants raised by asexual propagation reproduce the parent plant exactly, but there are a few exceptions to the rule," MONTAGUE FREE, *PLANT PROPAGATION IN PICTURES* 53 (1957) (listing several examples of exceptions).

<sup>66</sup> . It is hard to see a logical reason why that particular category should receive special treatment from a patent perspective.

<sup>67</sup> . "[T]he committee has, by its amendment in striking out the patenting of 'newly found' varieties of plants, eliminated from the scope of the bill these wild varieties discovered by the plant explorer or other person who has in no way engaged either in plant cultivation or care and who has in no other way facilitated nature in the creation of a new and desirable variety." S. REP. NO. 71-315, at 7 (1930).

<sup>68</sup> . Act of July 19, 1952, ch. 950, 66 Stat. 804.

requirement remained relaxed. To obtain a plant patent under § 161 a breeder must meet all of the requirements for § 101, except for the description requirement.<sup>69</sup>

In 1970, recognizing that true-to-type reproduction had become possible for sexually reproduced plants, Congress passed the Plant Variety Protection Act<sup>70</sup> (PVPA) to provide “patent-like protection to novel varieties of sexually reproduced plants (that is, plants grown from seed), which parallels the protection afforded asexually reproduced plant varieties (that is, varieties reproduced by propagation or grafting)” under the Plant Patent Act.<sup>71</sup> The PVPA was not intended to preempt other forms of protection.<sup>72</sup>

#### B. THE DESCRIPTION/ENABLEMENT SOLUTION

Congress solved the description and enablement problem by relaxing the general utility patent requirements. The statute was revised to provide that a patent which met the other requirements of the statute would not be invalid simply for failure to comply with the written description requirement “if the description is as complete as is reasonably possible.”<sup>73</sup> In 1930, no written description could have enabled creation of a plant, even if the ancestry and techniques of cross-pollination were

<sup>69</sup> . *J.E.M. Ag Supply v. Pioneer Hi-bred Int’l*, 534 U.S. 124 (2001); 35 U.S.C. § 161, ¶ 2 (2000) (“The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.”).

<sup>70</sup> . 7 U.S.C. § 2402(a) (1994). The Act was revised in 1994 to conform to the 1991 UPOV convention, to which the U.S. is a signatory, see B. Koo, C. Nottenburg & P.G. Pardey, *Plants and Intellectual Property: An International Appraisal*, 306 SCIENCE 1295 (2004).

<sup>71</sup> . *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 180 (1995).

<sup>72</sup> . *Pioneer Hi-Bred Int’l. v. DeKalb Genetics*, 51 U.S.P.Q.2d 1797, 1799 (S.D. Iowa 1999); see also MPEP, *supra* note 19, § 1601.

<sup>73</sup> . Act of May 23, 1930, ch. 312, sec. 2, § 4888, 46 Stat. 376. The comparable provision in the current statute is 35 U.S.C. § 162 (2000), which provides: “No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible. The claim in the specification shall be in formal terms to the plant shown and described.” The 35 U.S.C. § 112 requirement of enablement is satisfied for plants if the disclosure in the application is as complete as is reasonably possible. *In re LeGrice*, 301 F.2d 929 (C.C.P.A. 1962). The written description requirement of §112 is relaxed by § 162. *J.E.M. Ag Supply*, 534 U.S. at 127 (“To obtain a plant patent under § 161 a breeder must meet all of the requirements for § 101, except for the description requirement.”).

known—it was not possible to produce the plant from a disclosure contemplated by 35 U.S.C. § 112 for other types of manufactured articles. Thus, a reasonably complete description of the new plant variety is all that could be required. In addition, a patent applicant must allege characteristics that distinguish the plant from similar varieties.<sup>74</sup>

The general utility written description requirement serves several purposes, however. Not only does it serve the purpose of enabling others to make and use the invention (the purpose Congress thought impossible to meet), but it also serves to demonstrate that the invention has in fact been completed. In *Bourne v Jones*, the court recognized this second purpose, holding that obtaining a plant patent requires that the applicant: (1) invent or discover a new and distinct variety of plant and (2) asexually reproduce the plant.<sup>75</sup> Drawing on the utility patent requirement that an invention requires a mental step (conception of the invention), and a physical step (reduction to practice),<sup>76</sup> the court held that an invention must be based on something definite and certain and, thus, in the plant patent context, the invention of a new plant variety was not complete until the plant was grown to the point that its characteristics could be determined; one cannot claim a plant until he discovers that the characteristics described and claimed actually exist in the plant. An applicant bears the burden of clearly and precisely describing those characteristics which define the new variety as well as disclosing sufficient information to show that those characteristics are present in the plant and not in any other.

The characteristics that may distinguish a new variety would include, among others, those of habit; immunity from disease; or soil conditions; color of flower, leaf, fruit or stems; flavor; productivity, including ever-bearing qualities in case of fruits; storage qualities; perfume; form; and ease of asexual

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<sup>74</sup> . *In re Greer*, 484 F.2d 488 (C.C.P.A. 1973).

<sup>75</sup> . *Bourne v Jones*, 114 F. Supp. 413 (D.C. Fla. 1951), *aff'd* 207 F.2d 173 (5th Cir. 1953), cert. denied, 346 U.S. 897 (1953); *accord In re Greer*, 484 F.2d 488.

<sup>76</sup> . In addition, because an acceptable utility patent application must include an enabling disclosure, the application itself is considered a constructive reduction to practice, sufficient to complete the invention even in the absence of a physical reduction to practice. *Frazer v. Schlegel*, 498 F.3d 1283, 1287 (Fed. Cir. 2007).

reproduction. Within any one of the above or other classes of characteristics the differences which would suffice to make the variety a distinct variety, will necessarily be differences of degree.<sup>77</sup>

As summarized in the patent office regulations, the patent application “must contain as full and complete a disclosure as possible of the plant and the characteristics thereof that distinguish the same over related known varieties, and its antecedents, and must particularly point out where and in what manner the variety of plant has been asexually reproduced.”<sup>78</sup> The regulations require a “detailed botanical description”<sup>79</sup> and a single claim<sup>80</sup> although the statute requires neither.

Specimens of the plant, or its flower or fruit, in a quantity and at a time in its stage of growth as may be designated, must be furnished, if required, for study and inspection, although specimens “should not be submitted unless specifically called for by the examiner.”<sup>81</sup>

In *Ex parte Solomons*,<sup>82</sup> the Patent Office’s Board of Patent Appeals held that the deposit of a specimen of a microfungus with a public depository satisfied the “as complete as is reasonably possible” requirement under 35 U.S.C. § 162. More typically, however, the applicant addresses the disclosure requirement by providing a phenotypical description of selected characteristics of the plant, and such descriptions are routinely accepted provided the applicant discloses the defining physical characteristics of the plant and demonstrates how those characteristics distinguish the plant from others.<sup>83</sup>

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<sup>77</sup> . S. REP. NO. 71-315, at 4 (1930). Cases have added other characteristics to the list. See, e.g., *Imazio Nursery v. Dania Greenhouses*, 69 F.3d 1560 (Fed. Cir. 1995), *cert. denied*, 518 U.S. 1018 (1996) (resistance to cold, drought, heat, wind, or soil conditions); *Jessel v. Newland*, 195 U.S.P.Q. 678 (1977) (resistance to cold, drought, heat, wind, or soil conditions).

<sup>78</sup> . 37 C.F.R. § 1.163 (a) (2006).

<sup>79</sup> . 37 C.F.R. § 1.163 (c)(9) (2006).

<sup>80</sup> . 37 C.F.R. § 1.163 (c)(10) (2006).

<sup>81</sup> . 37 C.F.R. § 1.166 (2006). There are similar rules requiring deposit of microorganisms related to patent applications. If the applicant in a plant case has in fact made such a deposit, that may solve the enablement problem discussed in Part V. A., *infra*.

<sup>82</sup> . 201 U.S.P.Q. 42 (Bd. Pat. App. & Interf. 1978).

<sup>83</sup> . “[T]his court, recognizing present technological limitations, has concluded that there is no requirement for a how-to-make disclosure in a plant patent application.” *In re Greer*, 484 F.2d 488, 491 (C.C.P.A. 1973)



Congress did not specifically address the problem of identifying, and distinguishing from, prior art plants, leaving for the courts at least two questions: (1) on what basis would a plant be considered distinguished from other similar plants and (2) as between the first individual to observe and the first individual to propagate, who would be considered the inventor?

The legislative history suggests a partial answer to the first question. The Senate Report states: "In order for the new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties and it is immaterial whether in the judgment of the Patent Office the new characteristics are inferior or superior to those of existing varieties. Experience has shown the absurdity of many views held as to the value of new varieties at the time of their creation."<sup>84</sup> This suggests a broad range of distinguishing characteristics might be acceptable,<sup>85</sup> and subsequently issued patents indicate that the patent office in fact accepts a broad range of characteristics.<sup>86</sup> The Fifth Circuit defined "distinctness" as the aggregate of the plant's distinguishing characteristics.<sup>87</sup>

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(citing *In re LeGrice*, 301 F.2d 929, 944 (C.C.P.A. 1962)). The court in *Greer* continued:

Nevertheless, we do not agree that it was contemplated by Congress that its incorporation into R.S. 4888 of the matter which is the statutory predecessor to § 162 would operate to allow an applicant to allege characteristics which might be capable of distinguishing one variety of plant from another without sufficient disclosure to establish that these characteristics are indeed present in the claimed plant and absent in the varieties to which it is most closely related. . . .

[I]f, as is true in this case, the characteristics chosen to define the new plant are meaningless unless compared with predecessor plant varieties, it is incumbent upon the applicant to provide information of such a character that a meaningful comparison can be made. It is our view that the Patent Office in this case was justified in its conclusion that the criteria used to support the claim did not allow for such a meaningful comparison. . . .

*Id.*

<sup>84</sup> . S. REP. NO. 71-315, at 4 (1930).

<sup>85</sup> . See *supra* note 77 and accompanying text.

<sup>86</sup> . See *supra* text accompanying notes 46-52 discussing color (e.g., U.S. Plant Pat. 8), flavor (e.g., U.S. Plant Pat. 47), hardness (e.g., U.S. Plant Pat. 99), productiveness (e.g., U.S. Plant Pat. 11), and keeping qualities (e.g., U.S. Plant Pat. 3).

<sup>87</sup> . *Yoder Bros. v. Cal.-Fla. Plant Corp.*, 537 F.2d 1347, 1378 (5th Cir.

The answer to the second question is likewise suggested by the statutory requirement that “Any person who has . . . *invented or discovered and asexually reproduced* any distinct and new variety of plant . . . may . . . obtain a patent therefor.”<sup>88</sup> The issue arose before the patent office’s internal Board of Patent Appeals and Interferences in *Ex parte Moore*, where one individual had noticed a peach tree with unusual characteristics but did nothing to reproduce it, while a second individual (who noticed the unusual characteristics later) propagated the tree by cuttings.<sup>89</sup> The court noted that the objective of advancing the progress of science and useful arts was furthered by the party whose actions had preserved for posterity a variety that otherwise would have been lost and held that invention consisted of appreciating *and* asexually reproducing the new plant: the inventor is the one who appreciates that the plant is new and propagates it by asexual reproduction.<sup>90</sup>

In the case where two individuals work together, one of whom propagates the plant asexually, without recognizing its special properties, and the second of whom recognizes its properties, they are joint inventors. In *Bourne v. Jones*,<sup>91</sup> the court analogized the process of inventing a new plant with that of inventing a new chemical compound and concluded that the plant was jointly invented by the individual who propagated a series of sugar cane plants and the individual who selected the one from the series to pursue and determined its characteristics:

Ordinarily, invention is construed to mean a mental operation involving the conception of an idea, and a physical operation involving reduction to practice of the mental concept. . . . [F]rom the point of view of invention [of a plant], we have a situation

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1976), *cert. denied* 429 U.S. 1094 (1977).

<sup>88</sup> . Act of May 23, 1930, ch. 312, sec. 1, § 4886, 46 Stat. 376 (emphasis added). The comparable provision of the current patent statute is found in 35 U.S.C. § 161 (2006): “Whoever invents or discovers *and asexually reproduces* any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than . . . a plant found in an uncultivated state, may obtain a patent therefor . . . . (emphasis added).

<sup>89</sup> . *Ex parte Moore*, 115 U.S.P.Q. 145 (Bd. Pat. App. & Interf. 1957).

<sup>90</sup> . *Ex parte Moore*, 115 U.S.P.Q. at 147.

<sup>91</sup> . 114 F. Supp. 413 (D. Fla 1951) (finding joint inventorship and invalidating a patent since only one of the joint inventors was named in the application).

remarkably similar to the situation involved in the invention of a chemical compound. Because the properties or utilities of a new chemical compound cannot be definitely determined until the compound has been produced and tested for utility, it is usually held in such cases that conception and reduction to practice are simultaneous acts taking place at the time the characteristics and the utility of the compound are isolated and identified . . . . [T]he inventor of a chemical compound is held to be the one who first, by actual test or practice, determines the characteristics and utility of the compound. A scientific prediction of the compound's properties or utilities does not make the compound patentable.

The record is replete with expert opinion to the effect that only by tedious, repetitious tests can one be certain of the characteristics in a new variety of sugar cane . . . . Consequently, there could be no invention or discovery of these patented varieties of sugar cane prior to the time that the plants were grown and their characteristics determined . . . . One could not claim such a patent until he "discovers" that the characteristics described and claimed for the plant under the patent exist in the plant.<sup>92</sup>

There is one other possibility to consider—the possibility that the applicant's own work may constitute prior art, because the inventor delayed filing a patent application long enough after disclosure of the invention to constitute a statutory bar under 35 U.S.C. § 102(b). Under general utility patent rules, a disclosure constitutes a statutory bar only if it is enabling. The *In re LeGrice* court<sup>93</sup> held that a description of a patented *rosa floribunda* plant in a printed publication did not invalidate the patent since it was not enabling, even though it was the same plant. The mere disclosure of a photograph and description of characteristics was held not to be enough to place a skilled artisan in possession of the invention.

#### D. THE CLAIM SOLUTION

Also related to the description issue is the problem of drafting a sufficiently precise claim to the new plant.<sup>94</sup> Congress solved this problem by eliminating it, creating a *sui generis* claim requirement for plants. Plant patent claims are governed by § 162 rather than the general claim requirements of § 112, and need only claim the plant "in

<sup>92</sup> . *Id.* at 418–19 (citations omitted).

<sup>93</sup> . 301 F.2d 929 (C.C.P.A. 1962). While holding a photograph of a rose bush insufficient to enable the plant, the decision explicitly left open the possibility that in some future case a printed publication might be enabling.

<sup>94</sup> . Both issues arise under 35 U.S.C. §112 (2000).

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formal terms to the plant shown and described.”<sup>95</sup> The patent office interprets this requirement as satisfied by a claim of the form “I claim the new and distinct variety of (fill in the species) plant, substantially as illustrated and described herein”<sup>96</sup> and its rules provide “under no circumstances should the claim be directed to . . . fruit or flower in contradistinction to the plant bearing the flower or the tree bearing the fruit.”<sup>97</sup>

#### E. SUMMARY: THE PLANT PATENT REQUIREMENTS

Except as specifically modified by the PPA, the requirements of the general utility statute apply.<sup>98</sup> Thus, in order to receive a plant patent, an inventor must file an application with the U.S. Patent Office.<sup>99</sup> The application is reviewed by a patent examiner for compliance with the patent statute which requires a determination that the claimed subject matter:

1. is statutory subject matter, i.e., is a plant (within the commonly understood definition of the word) which has been asexually reproduced;
2. was found in a cultivated state;
3. has been asexually reproduced;<sup>100</sup>

<sup>95</sup> . 35 U.S.C. § 162 ¶ 2. This provision was added in 1952. Act of July 19, 1952, ch. 950, 66 Stat. 804.

<sup>96</sup> . MPEP, *supra* note 19, § 1605 final ¶ (“An example of a proper claim would be ‘A new and distinct variety of hybrid tea rose plant, substantially as illustrated and described herein.’”).

<sup>97</sup> . MPEP, *supra* note 19, § 1610 ¶ 2.

<sup>98</sup> . 35 U.S.C. § 161 (2000).

<sup>99</sup> . 35 U.S.C. § 111(a)(1) (2000).

<sup>100</sup> . “Asexual reproduction occurs by grafting, budding, or the like, and produces an offspring with a genetic combination identical to that of the single parent—essentially a clone.” *J.E.M. Ag Supply v. Pioneer Hi-bred Int’l*, 534 U.S. 124, 133 (2001). In *Imazio Nursery v. Dania Greenhouses*, 69 F.3d 1560 (Fed. Cir. 1995), *reh’g en banc denied*, 1996 US App LEXIS 2464, *cert. denied*, 116 S Ct 2549, the court defined asexual reproduction as isolation of a group or mass of vegetative cells from the parent plant that are capable of reproducing a plant that is genetically an exact duplicate of its parent plant, noting that Congress recognized that the asexual reproduction prerequisite greatly narrowed the scope of protection of plant patents but found such a limitation necessary to ensure that the characteristics of the plant to be patented were maintained—asexual reproduction confirms the existence of a new variety by separating variations resulting from fluctuations in environmental conditions from true plant variations. Post-1930 technology has added options for reliable propagation of true to type plants which would not have met the 1930 definition of asexual

4. is distinguishable from other known plants;
5. is described<sup>101</sup> and illustrated in the application in sufficient<sup>102</sup> detail; and
6. is claimed in a sufficiently specific manner.<sup>103</sup>

The theoretical differences between utility and plant patents are summed up by the Fifth Circuit:

Normally, the three requirements for patentability are novelty, utility, and non-obviousness. For plant patents, the requirement of distinctness replaces that of utility, and the additional requirement of asexual reproduction is introduced . . . The third requirement, *nonobviousness*, is the hardest to apply to plants. . . . The traditional three part test for obviousness, as set out in *John Deere* inquires as to (1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, and (3) the level of ordinary skill in the prior art. . . . Rephrasing the *John Deere* tests for the plant world, we might ask about (1) the characteristics of prior plants of the same general type, both patented and nonpatented, and (2) the differences between the prior plants and the claims at issue. We see no meaningful way to apply the third criterion to plants—i.e. the level of ordinary skill in the prior art. Criteria one and two are reminiscent of the “distinctness” requirement already in the Plant Patent Act. Thus, if we are to give obviousness an independent meaning, it must refer to something other than observable characteristics. We think that the most promising approach toward the obviousness requirement for plant patents is reference to the underlying constitutional standard that it codifies—namely, invention.<sup>104</sup>

### Under the PPA

an inventor—in principle—can obtain a patent on any plant . . .

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reproduction, for example apomixis, which involves producing genetically identical plants from seeds. Koltunow, Bicknell & Chaudhury, *Apomixis: Molecular Strategies for the Generation of Genetically Identical Seeds Without Fertilization*, 108 PLANT PHYSIOL. 1345, 1345-52 (1995).

<sup>101</sup> . Pan-American Plant Co. v. Matsui, 433 F. Supp. 693 (N.D. Cal. 1977) (disease resistance); *Ex parte* Rosenberg, 46 U.S.P.Q. 393 (Bd. Pat. App. & Interf. 1939) (difference in leaf texture and structure distinguished tobacco plant since flatter, more uniform leaf was preferable for cigar-wrapping purposes).

<sup>102</sup> . The Patent Office appears to have been satisfied that the sufficiency requirement was met, in the majority of recently issued plant patents, by reference to gross physical characteristics. Part IV. A., *infra* argues that, although this may be common practice, it does not meet the statutory requirements of 35 U.S.C. § 162 (2000).

<sup>103</sup> . Plant patent claims are formal and follow the formula: “I claim the new and distinct variety of (fill in the species) plant substantially as illustrated and described herein.” Thus, the sufficiency of the claim turns on the sufficiency of the illustration and description.

<sup>104</sup> . Yoder Bros v. Cal.-Fla. Plant Corp., 537 F.2d 1347, 1377-78 (5th Cir. 1976) (internal citations omitted).

that meets three requirements. It must be distinct; it must be new; and on one or more occasions it must have been "asexually reproduced," e.g., reproduced by means of a graft . . . the "asexual reproduction" requirement sought to ensure that the inventor was capable of reproducing the new variety "asexually" (through a graft) because that fact would guarantee that the variety's new characteristics had genetic (rather than, say, environmental) causes and would prove genetically stable over time.<sup>105</sup>

In holding that utility protection, as well as plant patent protection, was available for plants, the Supreme Court noted:

Whatever Congress may have believed about the state of patent law and the science of plant breeding in 1930, plants have always had the *potential* to fall within the general subject matter of § 101, which is a dynamic provision designed to encompass new and unforeseen inventions. "A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability."<sup>106</sup>

The Court's analysis continued:

Petitioners essentially ask us to deny utility patent protection for sexually reproduced plants because it was unforeseen in 1930 that such plants could receive protection under § 101. Denying patent protection under § 101 simply because such coverage was thought technologically infeasible in 1930, however, would be inconsistent with the forward-looking perspective of the utility patent statute. As we noted in *Chakrabarty*, "Congress employed broad general language in drafting § 101 precisely because [new types of] inventions are often unforeseeable."<sup>107</sup>

Between the Patent Office's 1985 decision that plants qualified for utility patent protection<sup>108</sup> and the Supreme Court's 2001 decision confirming that the PPA did not preempt the utility statute,<sup>109</sup> the PTO issued "some 1,800 utility patents for plants."<sup>110</sup>

#### F. THE INFRINGEMENT PRICE

Although Congress relaxed several disclosure standards for plants, it also modified the definition of infringement from a prohibition of manufacture, use or sale

<sup>105</sup> . *J.E.M. Ag Supply v. Pioneer Hi-bred Int'l*, 534 U.S. 124, 150 (2001) (Breyer, J., dissenting).

<sup>106</sup> . *Id.* at 135 (internal citations omitted).

<sup>107</sup> . *Id.* (internal citations omitted).

<sup>108</sup> . *Ex parte Hibberd*, 227 U.S.P.Q. 443, (Bd. Pat. App. & Interf. 1985).

<sup>109</sup> . *J.E.M. Ag Supply*, 534 U.S. 124.

<sup>110</sup> . *Id.* at 145.

of a product embodying the claimed invention to “the exclusive right to asexually reproduce the plant.”<sup>111</sup> As explained by the Supreme Court, “The PPA thus gave patent protection to breeders who were previously unable to overcome the obstacles described in *Chakrabarty*” but the protection was limited to asexually-reproduced plants, the only type which could be reproduced true-to-type at the time.<sup>112</sup>

A question remained as to whether the exclusive right to asexually reproduce “the” plant limited infringement to plants derived from the original plant which formed the basis for the patent, or extended to any plant which had the characteristics claimed in the patent.

The prevailing view is that to establish infringement of a plant patent, the patentee must prove that the alleged infringing plant is an asexually reproduced progeny of the patented plant<sup>113</sup> and that the infringement is complete when the propagation takes place—it is not necessary for the infringing plant to have reached maturity.<sup>114</sup> This view

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<sup>111</sup> . 35 U.S.C. § 163 (2000).

<sup>112</sup> . *J.E.M. Ag Supply*, 534 U.S. at 134. “All such plants must be asexually reproduced in order to have their identity preserved. This is necessary since seedlings either of chance or self-pollenization from any of these would not preserve the character of the individual.” S. REP. NO. 71-315, at 3 (1930).

<sup>113</sup> . *Van Well Nursery, Inc. v. Mony Life Ins. Co.*, 421 F. Supp. 2d 1321 (E.D. Wash. 2006).

In the present case, I am of the view that not only has the plaintiff failed to prove by clear and convincing proof that the trees grown by the defendant are an infringement upon his patent but that, on the contrary, there is ample proof to show that the trees grown by the plaintiff were a sport or mutation of the Le Grand tree. This conclusion is not in any way weakened by the testimony in the record given by a well-known scientist in the field of genetics that sports or mutations in the nectarine field are rare.

*Kim Bros. v. Hagler*, 167 F. Supp. 665, 669 (S.D. Cal. 1958), *aff’d* 276 F.2d 259 (9th Cir. 1960). “Conceding that the plants of the plaintiff and of the defendants have similar characteristics, the proof is not clear and convincing that the plaintiff must have appropriated plants or cuttings belonging to [plaintiff] or his assignee.” *Cole Nursery Co. v. Youdath Perennial Gardens*, 17 F. Supp. 159, 160 (N.D. Ohio 1936). *But see Pan-American Plant Co. v. Matsui*, 433 F. Supp. 693 (N.D. Cal 1977) (holding that a plant could infringe even though not a clone of the plant claimed in the patent).

<sup>114</sup> . *Yoder v. Cal.-Fla. Plant*, 537 F.2d 1347 (5th Cir. 1976), *cert. denied*. 429 U.S. 1094 (1977). (“On cross appeal, Cal-Florida asserts that the absence of flowering plants grown from the cuttings it had admittedly

is also logically consistent with the 1930s view that only asexual propagation assured preservation of the claimed characteristics.<sup>115</sup> Thus, to the extent that the description of physical characteristics represented a technologically imposed relaxation of the disclosure and enablement requirements of utility patent law, there is an offsetting compensation through the infringement provisions—the plant is not described well enough to enable others to independently make it, so if they do independently make it, it is not infringement. In *Imazio Nursery v. Dania Greenhouses*,<sup>116</sup> the Federal Circuit specifically recognized a defense of independent creation, holding that notwithstanding proof of the defendant's asexual reproduction of a plant having the same characteristics as the patented plant, the plain meaning of the statute required asexual reproduction of the patented plant for there to be infringement, and rejecting the trial court's concern that the "patent holder would have great difficulties enforcing his patent rights if a defendant were allowed to raise independent creation as an affirmative defense."<sup>117</sup>

This view also produces an internally consistent fiction. Patentable plants are limited to those produced by asexual

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taken from Yoder's patented plants was fatal to Yoder's infringement counts. This is because the patent claim in each instance describes a mature flowering plant, and it is Cal-Florida's position that only another mature flowering plant could directly infringe . . . . We agree with Yoder that it was not necessary to prove that the cuttings actually matured into flowered plants to show infringement. Under such a rule, it would be virtually impossible for a propagator-distributor directly to infringe a patent, despite the vital role he plays in dissemination of plant material.").

<sup>115</sup> . Congress recognized that the asexual reproduction prerequisite greatly narrowed the scope of protection of plant patents but found such a limitation necessary to ensure that the characteristics of the plant to be patented were maintained, since asexual reproduction confirms the existence of a new variety by separating variations resulting from fluctuations in environmental conditions from true plant variations. *Imazio Nursery v. Dania Greenhouses*, 69 F.3d 1560 (Fed. Cir. 1995), *reh'g en banc, denied*, 1996 US App LEXIS 2464, *cert. denied*, 116 S Ct 2549.

<sup>116</sup> . 69 F.3d 1560 (Fed. Cir. 1995), *reh'g, en banc, denied*, 1996 US App LEXIS 2464, *cert denied*, 116 S Ct 2549; see also *Van Well Nursery v. Mony Life Ins. Co.*, 421 F. Supp. 2d 1321 (E.D. Wash. 2006).

<sup>117</sup> . The district court was concerned that it would be difficult for the patentee to refute a defense of independent creation since the critical evidence would be in the alleged infringer's control.



propagation since this assures that the progeny will be identical to the parent plant and thus will, by definition, assure that each of the progeny will have the characteristics claimed to distinguish the patented plant. "Since a cutting is genetically identical to the parent plant, it will develop into a plant whose characteristics match the parent's exactly, so long as the same environmental conditions obtain."<sup>118</sup> It is internally consistent that if "asexual reproduction is literally the only way that a breeder can be sure he has reproduced a plant identical in every respect to the parent"<sup>119</sup> then the only way to be sure that an infringement has taken place is to tie it to the original, patented, plant.

#### IV. THE PROBLEM: 17,000 INVALID PATENTS?

Others have called for revisions to the plant patent statute, to provide greater clarity and stronger protection for genetic inventions.<sup>120</sup> In fact, "a special Presidential Commission, noting the special problems that plant protection raised and favoring the development of a totally new plant protection scheme, had recommended that 'all provisions in the patent statute for plant patents be deleted . . . .'"<sup>121</sup>

If the requirement of § 161 is read literally, so as to require an applicant for a plant patent to provide a "reasonably complete" description of the claimed plant, then applications which do not do so should not be granted and those which are granted should be declared invalid. Given the advances in plant technology described below,<sup>122</sup> it would appear that applications should have begun including genetic descriptions in lieu of (or in addition to) physical characteristics, possibly as early as 1960 but

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<sup>118</sup> . *In re LeGrice*, 301 F.2d 929 (C.C.P.A. 1962); *accord Yoder v. Calif-Fla. Plant*, 537 F.2d 1347, 1352 (5th Cir. 1976), *cert. denied*, 429 US 1094 (1977).

<sup>119</sup> . *Yoder*, 537 F.2d 1347, 1380.

<sup>120</sup> . See, e.g., Christopher E. James, Note, *The Impact on Agricultural Research by Genetic Material Patents and the Need for Clarity and Reform in Patent Law for Genetic Material*, 11 *DRAKE J. AGRIC. L.* 253 (2006).

<sup>121</sup> . *J.E.M. Ag Supply v. Pioneer Hi-bred Int'l*, 534 U.S. 124, 150 (2001) (Breyer, J., dissenting) (citing President's Commission on the Patent System, To Promote the Progress of Useful Arts, S. Doc. No. 90-5, at 20-21 (1967)).

<sup>122</sup> . See *infra* Part IV. B.

certainly beginning by 2000. A review of a sampling of plant patents indicates that this has not happened. Whether this means that roughly 17,000 plant patents are invalid depends on analysis of several issues:

1. Does the statute freeze “reasonableness” on the date of enactment in 1930 (or recodification in 1952), or is it a contemporary standard, advancing as technology advances?

2. If the standard is contemporary, has it changed since 1930 (and if so, what is it now)?

3. Is there a policy reason, based on administrative impossibility, which precludes examining patent applications which are based on genetic, rather than physical characteristic, descriptions?

4. Is there a policy reason, based on a desire not to invalidate essentially every plant patent issued in the last decade or two, to ignore technological advances since 1930?

#### A. DID THE PPA FREEZE THE STANDARD FOR DISCLOSURE AS OF ENACTMENT?

Section 162 absolves applicants for plant patents of the duty to provide an enabling disclosure of their inventions if “the description is as complete as is reasonably possible.” The provision was first enacted in 1930 and most recently considered in the 1952 recodification of the patent statute. Could Congress have intended to set, and freeze, the standard for reasonable possibility at either of those dates? Such an interpretation seems highly unlikely, for several reasons. First, when Congress recodified the statute in 1952, it did not indicate in the legislative history that it was also “resetting the clock” with respect to plant patent disclosure requirements—if the statute was intended to freeze the standard, one would expect such a statement. Furthermore, the patent statute is the vehicle for motivating technological progress and it would seem odd that a technology-motivating statute would freeze its standards for invention at a specific point in time.

In fact, two of the more common activities of patent examiners in reviewing applications are an evaluation of the claimed invention in comparison with the prior art<sup>123</sup> and (for utility patents) an evaluation of the sufficiency of

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<sup>123</sup> . The comparison is mandated by 35 U.S.C. §§ 102 & 103 (2000).

the disclosure.<sup>124</sup> Both evaluations are made as of a then-current date, not the date when the relevant statutory sections were enacted. While the issue does not appear to have been raised, the *J.E.M.*<sup>125</sup> case arguably provides inferential support for the contemporary technology standard, since it holds the 1930 Congress' incorrect belief, based on 1930 technology, irrelevant to the issue of preemption.<sup>126</sup>

It is no answer that, at the time of enactment, Congress did not foresee the genetic breakthroughs of the late 20th century. As the Supreme Court has noted:

Denying patent protection under § 101 simply because such coverage was thought technologically infeasible in 1930, however, would be inconsistent with the forward-looking perspective of the utility patent statute. As we noted in *Chakrabarty*, "Congress employed broad general language in drafting § 101 precisely because [new types of] inventions are often unforeseeable."<sup>127</sup>

In *J.E.M.*, the Court noted that although the legislative history of the Plant Patent Act suggests a general perception existed in 1930 that plants could not be patented:

"[t]his does not mean, however, that prior to 1930 plants could not have fallen within the subject matter of § 101. Rather, it illustrates only that in 1930 Congress *believed* that plants were not patentable under § 101, both because they were living things and because in practice they could not meet the stringent description requirement. Yet these premises were disproved over time. As this Court held in *Chakrabarty*, "the relevant distinction" for purposes of § 101 is not "between living and inanimate things, but between products of nature, whether living or not, and human-made inventions." *In addition, advances in biological knowledge and breeding expertise have allowed plant breeders to satisfy § 101's demanding description requirement.*<sup>128</sup>

The emphasized language makes clear that, while the statutory language regarding the level of disclosure required for a plant patent has not changed, the state of scientific knowledge has—this change in scientific knowledge translates into a heightened requirement for patentability. This is not an unusual occurrence in patent

<sup>124</sup> . The requirement for an adequate description for utility applications is mandated by 35 U.S.C. § 112 (2000).

<sup>125</sup> . *J.E.M. Ag Supply*, 534 U.S. 124.

<sup>126</sup> . See *supra* notes 30–38 and accompanying text.

<sup>127</sup> . *J.E.M. Ag Supply*, 534 U.S. at 135 (internal citations omitted).

<sup>128</sup> . *Id.* at 134 (internal citations omitted; emphasis added).

law. The general standard for patentability is set by reference to the then-current state of the art. The normal course of scientific progress dictates that discoveries which are astonishing and patentable in one era become commonplace and therefore unpatentable in a later era. While *J.E.M.* was concerned with patentability under § 101, the same argument applies to § 162, which exempts plant patents from the written description requirement of § 112 only “if the description is as complete as is reasonably possible.”<sup>129</sup> As scientific advances have made more complete descriptions “reasonably possible,” the statute requires applicants to provide them.

Thus, many issued plant patents are invalid for failure to meet the “do your best” requirement, because of natural developments which resulted in changes to what is “best.”

The above analysis indicates that there is an evolving standard of reasonableness, but only because Congress has chosen it. There does not appear to be a Constitutional mandate that the standard must continue to evolve.<sup>130</sup> Thus, if this is not the result Congress wants, it could clarify the statute to set a fixed date for determining the adequacy of plant patent disclosures. It could also provide a dividing line, possibly even a grace period allowing pending applications to be examined under one standard but future applications to be evaluated under a different standard.

#### B. WHAT IS THE CURRENT STATE OF THE ART IN REASONABLENESS?

If the standard for reasonableness progresses along with the progress of the relevant technology, it becomes important to establish how that standard has evolved from 1930 to the present, and how to determine the standard at any particular time.

When the PPA was enacted in 1930, Mendel’s theory of genetics was well-accepted, having gone through a period of doubt but then rehabilitated, and dictated that only

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<sup>129</sup> . 35 U.S.C. § 162 (2000) (“No plant patent shall be declared invalid for noncompliance with § 112 of this title if the description is as complete as is reasonably possible.”) .

<sup>130</sup> . One can construct an argument that motivating progress requires a “moving statutory target” in order to assure that a point will not be reached where no further progress is possible. The argument does not seem compelling.

asexual propagation would assure true-to-type reproduction of the physical characteristics of a plant; sexual propagation would result in hybrids, some of which would resemble one parent, some of which would resemble the other parent and some of which would resemble neither. While it was understood that genetics played a controlling role in determining those characteristics, the connection between DNA and genetics was unknown. The standard for describing and categorizing plants was based on observable physical characteristics—the phenotype which was the result of the then unobservable genetic code which produced it.

It was not until 1935 that Andrei Belozersky isolated DNA. The structure (as opposed to chemical composition) of DNA remained a puzzle until James Watson and Francis Crick discovered its double helical structure<sup>131</sup> and reported it in *Nature* in 1953. They received the 1962 Nobel Prize for the discovery. Starting in the mid-1960's, efforts were made to distinguish plants based on chemical components.<sup>132</sup> The manner in which the DNA molecule controlled the production of amino acids was discovered by Marshall Nirenberg in 1966. David Botstein discovered that, when the DNA from different people was cut using a restriction enzyme, certain of the resulting fragments had different lengths.<sup>133</sup> The reliability of the technology in identifying individuals as the source of a DNA sample was accepted in a U.S. criminal case in 1987.<sup>134</sup> A conviction based on DNA evidence was affirmed by a state court of

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<sup>131</sup> . The discovery was made on February 28, 1953.

<sup>132</sup> . "During the last 40 years, there has been sustained interest in the ability to identify individual hop varieties by the essential oil and resin components . . . Since 1982, the composition of essential oils has been studied at the Institute for Hop Research and Brewing Zalec. . ." Cerenak et. al., *Identification and Differentiation of Hop Varieties Using Simple Sequence Repeat Markers*, 62 J. AM. SOC. BREW. CHEM. 1 (2004). However, "[i]t was shown that the organoleptic evaluation is fairly subjective. . ." *Id.*

<sup>133</sup> . The fragments are referred to as Restriction Fragment Length Polymorphisms (RFLPs) and, with the addition of genetic enhancement techniques, such as PCR, became the basis for "DNA fingerprinting" (invented by Alec Jeffreys in 1984). An alternative identification technology, Expressed Sequence Tags (ESTs) was at the center of controversy when, in 1997, the patent office announced that it would consider patents for ESTs.

<sup>134</sup> . *Andrews v. State*, 533 So. 2d 841 (Fla Dist. Ct. App. 1988).

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 last resort in 1989.<sup>135</sup> In December, 1999, *Nature* carried the news of completion of the first complete DNA sequence of a plant chromosome,<sup>136</sup> which was followed a year later with the “cracking” of the human genetic code.<sup>137</sup> Researchers have continued to sequence other plant species’ DNA using a variety of techniques.<sup>138</sup> In the comparable area of patents for gene sequences, there has been dramatic growth. Between 1980 and 2000, just 2,000 patents were issued for gene and gene sequences. Recently, more than 70,000 applications were pending before the United States Patent and Trademark Office (USPTO) for similar patents.<sup>139</sup>

<sup>135</sup> . State v. Woodall, 385 S.E.2d 253 (W. Va. 1989).

<sup>136</sup> . K. Mayer et al., *Sequence and Analysis of Chromosome 4 of the Plant Arabidopsis Thaliana*, 402 *NATURE* 769 (1999); Xiaoying Lin et al., *Sequence and Analysis of Chromosome 2 of the Plant Arabidopsis Thaliana*, 402 *NATURE* 761 (1999). A press release was issued by the National Science Foundation’s Office of Legislative and Public Affairs on December 15, 1999; the *Nature* article appeared on December 16. Press Release, Nat’l Sci. Found., Scientists Report First Complete DNA Sequence of Plant Chromosomes, (Dec. 15, 1999), available at <http://www.nsf.gov/pubs/2000/pr9973/pr9973.txt>. An earlier advance toward the complete sequence was reported in 1993. Holte et. al., *An Inventory of 1152 Expressed Sequence Tags Obtained from Partial Sequencing of cDNAs from Arabidopsis Thaliana*, 4 *PLANT J.* 1051 (1993) (“these results underscore the efficiency with which new plant genes can be identified through partial sequencing of anonymous DNAs”).

<sup>137</sup> . The first plant chromosome completed was *Arabidopsis thaliana*, which has an approximately 125 Megabase genome. In contrast, the human genome consists of roughly 3 billion base pairs.

<sup>138</sup> . See, e.g., Slightom et. al., *Complete Nucleotide Sequence of a French Bean Storage Protein Gene: Phaseolin*, 80 *PROC. NAT’L ACAD. SCI.* 1897 (1983); Theologis, et. al., *Sequence Analysis of Chromosome 1 of the Plant Arabidopsis Thaliana*, 408 *NATURE* 816 (2000); Cerenak et. al., *Identification and Differentiation of Hop Varieties Using Simple Sequence Repeat Markers*, *J. AM. SOC. BREW CHEM.* 1 (2004) (“Randomly amplified polymorphic DNA (RAPD), sequenced tag sites (STS) markers, and microsatellites have been used to some extent for identity typing and hop cultivar identification.”). Citing RAPD studies from 1991 and 1994, an STS study from 1998 and microsatellite studies from 1996 and 2001, Cerenak et al. report that “five polymorphic microsatellites are capable of differentiating among all cultivars included, except cultivars derived from clonal selection, polyploidy, or mutations.” *Id.* at 7. Bausher, et. al., *The Complete Chloroplast Genome Sequence of Citrus Sinensis (L.) Osbeck var ‘Ridge Pineapple’: Organization and Phylogenetic Relationships to Other Angiosperms*, 6 *BMC PLANT BIOLOGY* 21 (2006) (comparing DNA and EST sequences). “We have sequenced the *Citrus* chloroplast genome to facilitate genetic improvement of this crop.” *Id.*

<sup>139</sup> . James, *supra* note 120, at 256.

## C. TWO CONSEQUENCES FOLLOW

The rationale for limiting plant patents to asexual reproduction is explained in the Senate Report accompanying the bill: "All such plants must be asexually reproduced in order to have their identity preserved. This is necessary since seedlings either of chance or self-pollination from any of these would not preserve the character of the individual."<sup>140</sup> Post-1930 technology has added options for reliable propagation of true-to-type plants which would not have met the 1930 definition of asexual reproduction, for example apomixis, a technique for producing genetically identical plants from the seeds of certain types of plants.<sup>141</sup> In fact, apomixis may offer advantages over vegetative propagation: "Clonal seed would help avoid costly and time-consuming vegetative propagation methods that are currently used to ensure the large scale production of these crops."<sup>142</sup> Research is underway to develop techniques for enabling apomixis in plants which do not have the capability naturally.<sup>143</sup> Thus, the first consequence is that the range of reproduction techniques covered by the PPA must be expanded to include modern techniques, and not be limited to techniques considered by the 1930 Congress.

The second consequence which follows is that the emerging standard of disclosure has undergone several changes since 1930. While there may be legitimate debate over the exact date when a particular change occurred, it is clear that sometime after the mid-1960's, at least some plant patent applications (those which claimed distinction from the prior art based on such factors) should have provided chemical analyses of the claimed plant and of the nearest prior art plants.<sup>144</sup> It is also clear that sometime

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<sup>140</sup> . S. REP. NO. 71-315, at 3 (1930). Asexual propagation "is a term applied to the propagation of plants from parts other than seeds or spores." MONTAGUE FREE, PLANT PROPAGATION IN PICTURES 53 (1957).

<sup>141</sup> . Anna M. Koltunow, Ross A. Bicknell, & Abdul M. Chaudhury, *Apomixis: Molecular Strategies for the Generation of Genetically Identical Seeds Without Fertilization*, 108 PLANT PHYSIOLOGY 1345 (1995).

<sup>142</sup> . *Id.* at 1346.

<sup>143</sup> . *Id.* at 1351.

<sup>144</sup> . "During the last 40 years, there has been sustained interest in the ability to identify individual hop varieties by the essential oil and resin components . . . Since 1982, the composition of essential oils has been studied at the Institute for Hop Research and Brewing Zalec . . ."

after the December, 1999, *Nature* article reporting a complete DNA sequence of a plant chromosome and subsequent perfection of other DNA-based plant identification techniques,<sup>145</sup> the standard would require that a plant patent application include disclosure of DNA sequences.

#### D. CAN THE SYSTEM HANDLE VALID DISCLOSURES?

Notwithstanding the above analysis, it would make no sense to require a type of disclosure which the patent office was incapable of evaluating. One of the challenges for examination of plant patent applications is the difficulty of finding relevant prior art. Under the 1930 “physical characteristic” standard, the problem is identifying prior art plants and comparing sometimes subjective characteristics; under a 21st century DNA based standard, the problem will be locating appropriate databases and a language which facilitates comparison. The statute (and President Hoover’s executive order) provided for the assistance of the Department of Agriculture,<sup>146</sup> which presumably has expertise in both areas. Databases which are well-suited to this type of analysis are already maintained by the National Institutes of Health (NIH).<sup>147</sup>

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Cerenak et. al., *supra* note 138, at 1. However, “[i]t was shown that the organoleptic evaluation is fairly subjective . . .” *Id.*

<sup>145</sup> . See Press Release, Nat’l Sci. Found., Scientists Report First Complete DNA Sequence of Plant Chromosomes, (Dec. 15, 1999), available at <http://www.nsf.gov/pubs/2000/pr9973/pr9973.txt>. Earlier dates are also arguable: 1993, the date of the Holte article in *The Plant Journal*, *supra* note 136; 1988, the date when *Andrews* was decided, *supra* note 134; or 1989, when the appellate court acknowledged the reliability of DNA testing in *Woodall*, *supra* note 135, or some “reasonable” period of time following each of these events.

<sup>146</sup> . *In re Greer*, 484 F.2d 488, 489 (C.C.P.A. 1973) (“In conformance with the usual procedure for the examination of applications for plant patents, the application was submitted by the Patent Office to the Department of Agriculture for its evaluation of the assertions made in the specification supporting the claim that the grass was a distinct and new variety of plant. In due course a report was provided by the Department of Agriculture to the Patent Office . . .”).

<sup>147</sup> . One example is the BLAST program, which provides a library of known DNA and related sequences and software for entering a new sequence and determining whether a similar one already exists in the database. See, e.g., National Center for Biotechnology Information, Basic Local Alignment Search Tool (BLAST), [http://www.ncbi.nlm.nih.gov/blast/Blast.cgi?CMD=Web&PAGE\\_TYPE=BlastHome](http://www.ncbi.nlm.nih.gov/blast/Blast.cgi?CMD=Web&PAGE_TYPE=BlastHome) (last visited Mar. 15, 2008).



Moreover, this is a challenge of a type which the USPTO has faced successfully before. In 1996, Commissioner Lehman reported on the administrative aftermath of the Supreme Court's *Chakrabarty* decision: "For over a decade, the PTO has been examining and granting patents to claims reciting nucleic acid sequences."<sup>148</sup> The most recent challenge to the PTO's ingenuity in examining new technologies was the Federal Circuit's decision in *State Street Bank*.<sup>149</sup> In response to that decision, which held business method patents statutory, the PTO tripled the number of examiners assigned to the field and identified new databases to be searched in determining patentability.<sup>150</sup> There was a learning curve, manifested in a longer than average delay in initially acting on business method patents while the PTO adjusted, but by the end of 2001 the average pendency of a business method application was within three months of the overall PTO average.<sup>151</sup> Thus, the PTO faces a problem of execution,

<sup>148</sup> . Bruce A. Lehman, Assistant Sec'y of Commerce and the Comm'r of Patents and Trademarks, Public Hearing on Patenting of Nucleic Acid Sequences (Apr. 23, 1996) (transcript available at <http://www.uspto.gov/web/offices/com/sol/notices/seq-hear.txt>).

<sup>149</sup> . *State Street Bank & Trust Co. v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998).

<sup>150</sup> . U.S. PATENT & TRADEMARK OFFICE, A USPTO WHITE PAPER: AUTOMATED FINANCIAL OR MANAGEMENT DATA PROCESSING METHODS (BUSINESS METHODS) 9-21 (2000), available at <http://www.uspto.gov/web/menu/busmethp/index.html>. In the two years from the Federal Circuit decision to the publication of the White Paper, the PTO had increased the number of examiners in Class 705 from twelve to thirty-eight and reported that "Seventeen of the 38 examiners have advanced or multiple degrees. Of these 4 have an MBA or other business degrees, 4 have a JD degree, 4 have Ph.D. degrees, and 7 have Masters Degrees." *Id.* at 14. The PTO had also identified databases of non-patent literature (NPL) which examiners are to consult in addition to searching the patent database, including Dialog and the Software Patent Institute and the IEEE/IEE Electronic Library databases. *Id.* at 21. See also U.S. Patent & Trademark Office, Business Methods Still Experiencing Substantial Growth—Report of Fiscal year 2001 Statistics, <http://www.uspto.gov/web/menu/pbmethod/fy2001strport.html> (last visited Mar. 19, 2008).

<sup>151</sup> . "The average pendency to first action in Class 705 is 23.5 months. This can be compared to an average pendency to first action of 14.6 months for the entire USPTO. The average time to disposal is 28.5 months in Class 705. This can be compared to an average time to disposal of 25.6 months for the entire USPTO." U.S. Patent & Trademark Office, Business Methods Still Experiencing Substantial Growth—Report of Fiscal year 2001 Statistics, <http://www.uspto.gov/web/menu/pbmethod/fy2001strport.html> (last visited Mar. 19, 2008).

not theory. In addition, it has tools at its disposal to facilitate execution and can draw on expertise from other agencies, such as the Department of Agriculture, the Food and Drug Administration and the NIH.

#### E. CAN THE SYSTEM TOLERATE INVALIDATING 17,000 PATENTS?

Notwithstanding the statutory command and the ability of the responsible agency to carry it out, the consequent invalidity of a large number of patents is a factor to consider. It would be awkward for a system designed to promote progress by providing economic incentives to deprive innovators of that incentive on a wholesale basis. One answer would be that the core principles of patent law require an exchange: the economic incentive is provided, not for innovation, but for disclosure—if the disclosure is inadequate, the incentive has not been earned. The problem is not completely unanticipated—it has at least been hinted at in early cases:

While the present knowledge of plant genetics may mean as a practical matter, that the descriptions in such general publications as are here involved cannot be relied upon as a statutory bar . . . we must be mindful of the scientific efforts which are daily adding to the store of knowledge in the fields of plant heredity and plant eugenics which one skilled in this art will be presumed to possess . . . . Current studies to “break the chromosome code” may also add to the knowledge of plant breeders so that they may someday secure possession of a plant invention by a description in a printed publication as is now possible in other fields of inventive effort.<sup>152</sup>

Fortunately, there are avenues for accomplishing both objectives: rescuing many of the patents that would otherwise be invalid, and obtaining the disclosure.

### V. CONSEQUENCES OF A 21st CENTURY APPROACH

#### A. WHAT CAN BE DONE FOR EXISTING PATENTS AND APPLICATIONS?

What can be done to “save” invalid plant patents, and pending applications that cannot lead to a valid patent, depends on the stage the applicant has reached. Applications which have not yet been filed offer the greatest chance for validity, followed by pending

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<sup>152</sup> . *In re LeGrice*, 301 F.2d 929, 941 (C.C.P.A. 1962) (internal footnote omitted).

applications, patents issued less than two years ago and finally patents issued more than two years ago.

### 1. Unfiled Applications

Unfiled applications offer the greatest opportunity for producing a valid patent. Those applications can be drafted to include a distinguishing genetic sequence or can be supported by a deposit of genetic material in a publicly accessible facility.

### 2. Pending Applications

Those applications which include genetic sequences, or which included a deposit of a sample of the plant, comply with the requirements of disclosure and need do nothing further. Those which do not face the problem that, as filed, the application is insufficient. Once an application for a patent has been filed, the ability to amend it is limited: changes may be made, but "new matter" may not be added. However, with respect to plant patents, an internal patent office rule provides

if the written description is deficient, "a clarification or additional description of the plant, or even a wholesale substitution of the original description so long as not totally inconsistent and unrelated to the original description and photograph of the plant may be submitted in reply to an Office action." *Such submission will not constitute new matter* . . .<sup>153</sup>

Thus, many pending applications can be saved by providing additional description of the plant, consisting of appropriate DNA sequence information. This could be facilitated (and the argument for validity strengthened) if the patent office requested such clarification in an office action. Alternatively, the patent office could exercise its authority to request specimens of the plant.

### 3. Issued Patents: Less than Two Years Out

The patent statute permits a patentee to request a broadening reissue within two years from the issue date of the patent. Patentees in this category could file such a request and follow the procedure outlined above.

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<sup>153</sup> . MPEP, *supra* note 19, § 1605 (citing *Jessel v. Newland*, 195 U.S.P.Q. 678, 684 (Dep. Comm'r Pat. 1977)) (emphasis added).

## 4. Issued Patents: More than Two Years Out

There does not appear to be any procedure under the current statute for “rescuing” patents which were issued more than two years ago. Moreover, given the number of patents which might be saved under one of the above procedures, the policy reasons for facilitating their rescue, and the burden that thousands of amendments and requests for reissue would place on patent office resources, Congress might well want to solve the problem legislatively. It could, for example, amend the statute to provide a future effective date for specifically requiring genetic information, while grandfathering applications filed before that date.

## B. REDEFINING WRITTEN DESCRIPTION

The written description requirement has two roles with respect to patents: description and enablement. Including a DNA sequence not only provides a contemporary description which is better than the historical physical description, but may also at some point in the future provide the basis for enablement. Thus, should Congress choose to “save” defective applications, it should require that the applications be supplemented with the best DNA information available.

## C. REDEFINING WHAT CAN BE CLAIMED

There is a potential benefit for plant inventors. Current patent rules provide “under no circumstances should the claim be directed to . . . fruit or flower in contradistinction to the plant bearing the flower or the tree bearing the fruit.”<sup>154</sup> This limitation made sense in the context of physical descriptions.<sup>155</sup> However, if the plant is defined, not by gross physical properties but by genetic makeup, there is no principled reason why the claim could not be to the entire plant or any part thereof, since all parts of the same plant would share the same DNA. Thus, the statute could be amended to permit multiple claims in a plant patent.

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<sup>154</sup> . *Id.* § 1610 (second paragraph).

<sup>155</sup> . See *supra* notes 73–83 and accompanying text.

In 1930, Congress felt it had no choice but to provide special statutory provisions to protect inventors of plants. Those special provisions allowed simplified, and approximate, disclosure but limited protection compared with general utility patents.

It is no longer necessary to use approximations. Better disclosures, with potential benefits to the public, are now possible. The patent office and courts should demand those better disclosures. In many cases, this can be accomplished under existing law. To the extent Congress finds the results to be poor public policy, it has the power to amend the statute to provide temporary relief. In addition, Congress can also provide broader protection to plant inventors in exchange for the better disclosures which technological advances have made possible.